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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 23 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Section 18, For Use of Vinclozolin in Pennsylvania on Snapbeans

FROM: John Tice
Occupational and Residential Exposure Branch
Health Effects Division (H-7509-C)

TO: Linnea Hansen,
Toxicology Branch I
Health Effects Division (H-7509-C)

THRU: Mark I. Dow, Ph.D., Section Head
Special Review and Registration Section II
Occupational and Residential Exposure Branch
Health Effects Division (H-7509-C)

Larry Dorsey, Chief
Occupational and Residential Exposure Branch
Health Effects Division (H-7509-C)

Please find below, the OREB review of:

DP Barcode: D-187996

Pesticide Chemical Code: 113201, Vinclozolin, Ronilan DF.

EPA Reg. No.: 7969-85

EPA MRID No.: Four studies referenced.

PHED: YES

REFERRED TO TOX I FOR RISK ASSESSMENT

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I. INTRODUCTION:

Background/Purpose

The State of Pennsylvania requested permission under Section 18 provisions of FIFRA to use vinclozolin on snapbeans to control fungal diseases. This request is similar to several other requests received by the Agency for the same use in other states.

II. DETAILED CONSIDERATIONS:

A. Use

Snapbeans in Pennsylvania are generally grown on 20 acre plots. Some farms may have as many as 80 acres planted in snapbeans, however, they generally stagger plantings of about 20 acre sections so that bean harvesting is staggered. Additionally, the total crop is not exposed to the same disease pressure.[1] State plant protection specialists are recommending applications of from 0.5 to 0.75 lb ai per acre. to control diseases. This review evaluates exposures from making one (daily) application to 20 acres and additionally from treating 200 acres over several days as a custom applicator might do.

B. Toxicology concerns

Vinclozolin is classified as a tox category IV chemical for acute oral toxicity with an LD_{50} of > 10 g/kg (highest dose tested) and as a Tox category III chemical for acute dermal toxicity with an LD_{50} of > 2.5 g/kg HDT. The Toxicology concern of note is pseudohermaphroditism which is manifested in a decreased anal-genital distance in male fetuses.

C. Prior exposure reviews

Numerous prior reviews are in the Branch files. All reviews to date use standard surrogate data to estimate exposures. This review uses PHED exposure estimates derived by the PHED task force.

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[1] Personal communication with Mr. Mark Bierly, Tri-Co Foods, Center Hall, PA; Phone: 814-364-9217.

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In response to the request to evaluate new data and incorporate that data in this review, OREB has not completed the review of the data and thus it is not ready to be used to support a regulatory decision.

D. Detailed exposure calculations

Exposure calculations are based on the following assumptions:

- Average worker has the mass of 70 kg. (Although Toxicology has concerns over developmental effects, a man's weight is being used because most applications will be performed by male custom applicators.
- mixer/loader and applicator can be the same person (see combined exposure) for the treatment of 20 acres. However, this may not be the case as more acreage is treated.
- respiratory exposure is negligible compared to dermal exposure and is combined with dermal exposure,
- dermal exposure is not adjusted for dermal absorption,
- for persons handling and applying this product, standard work clothing is worn which includes coveralls, protective gloves (mixing and loading only), long-sleeved shirts, long pants, goggles/face shield,
- the average treated acreage sprayed by any one person (average farm) is 20 acres, and in one day a single person will mix/load and spray a maximum of 20 acres at 0.75 lbs ai per acre,
- the maximum application rate is used during each of four applications @ 0.75 lb ai/acre.
- Pesticide Handlers Exposure Database (PHED) was used to estimate unit exposures.

The following table summarizes daily and annual exposures for mixer/loader, applicator, and mixer/loader/applicator, using the "open pour" loading system.

WORKER EXPOSURES TO VINCLOZOLIN

OPERATION	UNIT EXPOSURE μg/lb handled	GROSS EXPOSURE[2] 20 ACRES (μg a.i.)	DAILY EXPOSURE[3] (20 ACRES) μg/kg	TOTAL YEARLY EXPOSURE[4] μg/kg	ANNUAL DAILY EXPOSURE[5] μg/kg/day
M/L OPEN LOAD	414.3	6,214.50	88.78	355.11	0.97
GROUND AP. 20 ACRES	32.2	483.00	6.90	27.60	0.08
AERIAL APPLICATOR	5.9	88.50	1.26	5.06	0.01
M/L/A GROUND, 80 ACRES	446.5	6,697.50	95.68	382.71	1.05

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[2] **Exposure resulting from handling 15 lbs ai; enough to spray 20 acres @ 0.75 lbs ai/acre.**

[3] **Daily exposure estimate for handling 15 lbs ai. Estimates calculated using the following formula:**

$$\frac{Unit\ Exposure * (15\ lbs\ ai)}{70\ kg.\ bw.} = Daily\ Exposure$$

[4] **Exposure from four (4) applications @ 0.75 lb. ai/acre to 20 acres calculated by the following equation:**

$$\frac{Unit\ Exposure\ *\ (15\ lbs\ ai * 4\ applications)}{70\ kg.\ bw.} = Total\ Yearly\ Exposure$$

[5] $$\frac{Total\ Yearly\ Exposure}{365\ Days} = Annual\ Daily\ Exposure$$

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III. CONCLUSIONS:

- The maximum acute exposure to a person (adult male) mixing, loading, and applying 15 lbs of ai to 20 acres is estimated to be 95.68 μg/kg/day. After making three (3) additional applications, the annualized daily exposure is estimated as 1.05 μg/kg/day.

cc: Correspondence File
Vinclozolin File (113201)

APPLICATOR EXPOSURE

Inhalation Exposure:

SUMMARY STATISTICS FOR INHALATION EXPOSURES

	DISTRIB. TYPE	NANOGRAMS PER LB AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs.
EXPOSURE	Lognormal	844.7968	5127.6701	184.6024	**1252.4861**	56

Number of Records: 56 Data File: APPLICATOR
Subset Name: GB.OPEN.AIR.APPL

Dermal Exposure:

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES
SCENARIO: Long pants, short sleeves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Lognormal	7.02	27.1548	188.6086	5.4023	77
NECK.FRONT	Lognormal	.705	3.3384	205.934	.5523	75
NECK.BACK	Lognormal	.3905	2.4527	199.368	.3761	74
UPPER ARMS	Other	.291	.291	0	.291	6
CHEST	Other	.71	6.6813	205.7953	1.621	39
BACK	Other	2.13	9.3188	181.4676	1.9108	24
FOREARMS	Lognormal	8.107	22.1823	177.1191	5.2029	77
THIGHS	Other	.382	1.0641	165.5202	.5749	14
LOWER LEGS	Other	.238	1.615	232.805	.4201	14
FEET						0
TOTAL DERM:	**15.2849**					

Number of Records: 83
Data File: APPLICATOR Subset Name: GB.OPEN.APPL

Hand Exposure:

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES
SCENARIO: no gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs.
HANDS	Lognormal	20.8676	72.7166	224.686	**15.6989**	60

Number of Records: 71 Data File: APPLICATOR
Subset Name: GB.OPEN.HANDSA_E.APPL

Total Exposure:
long pants, short sleeves, no gloves = **32.24 ug/lb ai**

MIXER/LOADER EXPOSURE

Inhalation Exposure:

SUMMARY STATISTICS FOR INHALATION EXPOSURES

	DISTRIB. TYPE	NANOGRAMS PER LB AI MIXED Median	Mean	Coef of Var	Geo. Mean	Obs.
EXPOSURE	Lognormal	567.3838	33561.7846	369.5727	**871.5879**	24

Number of Records: 24 Data File: MIXER/LOADER
Subset Name: DF.WP.DST.OPEN.AIR.MLOD

Dermal Exposure:

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES
SCENARIO: Long pants, short sleeves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI MIXED Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Normal	37.18	56.7225	100.7641	21.2457	55
NECK.FRONT	Normal	9.03	11.6133	97.4727	4.3796	55
NECK.BACK	Lognormal	2.431	4.399	126.5469	1.246	55
UPPER ARMS	Lognormal	105.4875	824.694	195.8269	211.7187	6
CHEST	Lognormal	15.0875	408.9304	299.2262	8.0635	12
BACK	Lognormal	15.0875	421.9767	294.5983	6.6877	12
FOREARMS	Other	100.793	406.5473	328.4836	79.279	57
THIGHS	Lognormal	16.044	23.684	136.7518	3.9707	10
LOWER LEGS	Other	.238	8.0444	125.2797	1.3939	10
FEET						0

TOTAL DERM: **401.0534**
Number of Records: 57 Data File: MIXER/LOADER
Subset Name: DF.WP.DST.OPEN.DERM.A_E.MLO

Hand Exposure:

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES
SCENARIO: gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI MIXED Median	Mean	Coef of Var	Geo. Mean	Obs.
HANDS	Lognormal	11.5495	14.6341	78.8364	**12.4163**	20

Number of Records: 22 Data File: MIXER/LOADER
Subset Name: DF.WP.DST.OPEN.HANDAB.MLOD

Total Exposure:

long pants, short sleeves, gloves = **414.34 ug/lb ai**

AERIAL APPLICATION EXPOSURE

Total Exposure:

Long pants, short sleeves, no gloves = 5.9 ug/lb ai

Inhalation Exposure:

SUMMARY STATISTICS FOR INHALATION EXPOSURES

	DISTRIB.	NANOGRAMS PER LB AI SPRAYED				
	TYPE	Median	Mean	Coef of Var	Geo. Mean	Obs.
EXPOSURE	Lognormal	134.7952	468.750	226.6519	**165.9224**	25

Number of Records: 25 Data File: APPLICATOR
Subset Name: AERFWRW.AIR.APPL

Dermal Exposure:

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES
SCENARIO: Long pants, short sleeves

PATCH	DISTRIB.	MICROGRAMS PER LB AI SPRAYED				
LOCATION	TYPE	Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Other	.455	1.3683	172.2575	.5132	40
NECK.FRONT	Lognormal	.045	.1061	144.8633	.0529	40
NECK.BACK	Lognormal	.0385	.0622	164.4695	.0324	32
UPPER ARMS	Other	.291	.291	0	.291	6
CHEST	Other	.355	.3905	28.758	.3805	10
BACK	Other	.355	.355	0	.355	10
FOREARMS	Other	.484	1.1334	210.1641	.3893	30
THIGHS	Other	.382	.382	0	.382	6
LOWER LEGS	Other	.238	.238	0	.238	6
FEET						0

TOTAL DERM: **2.6453**
Number of Records: 40 Data File: APPLICATOR
Subset Name: AERFWRW.DERMA_E.APPL

Hand Exposure:

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES
SCENARIO: no gloves

PATCH	DISTRIB.	MICROGRAMS PER LB AI SPRAYED				
LOCATION	TYPE	Median	Mean	Coef of Var	Geo. Mean	Obs.
HANDS	Lognormal	2.2666	12.7278	206.1244	**3.0849**	22

Number of Records: 28 Data File: APPLICATOR
Subset Name: AERFWRW.HANDABC.APPL

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